K122844

510(k) SUMMARY

OCT 17 2012

SUBMITTER:

Sorin Group Italia
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

Luigi Vecchi
Phone: 39 0535 29811
Fax: 39 0535 25229

DATE PREPARED: September 14, 2012

DEVICE TRADE NAME: INSPIRE 8F DUAL hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir

COMMON NAMES:
Hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir
Hollow Fiber Oxygenator with integrated arterial filter Hardshell Venous/Cardiotomy Reservoir

CLASSIFICATION NAME:
Cardiopulmonary Bypass Oxygenator/
Cardiopulmonary Bypass Heat Exchanger/
Cardiopulmonary Bypass Blood Reservoir/
Cardiopulmonary Bypass Defoamer
Cardiopulmonary Bypass Arterial Line Blood Filter

UNMODIFIED DEVICES: INSPIRE 8F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir (K121536)

DEVICE DESCRIPTION:

The INSPIRE 8F DUAL is a high efficiency microporous hollow fiber membrane oxygenator integrated with an arterial filter and a heat exchanger (INSPIRE 8F M) and connected to a hardshell venous/cardiotomy reservoir (INSPIRE HVR DUAL). A molded fitting joint connects the oxygenator to the reservoir.

The device can be operated at flow rates up to 8 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli and the integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.
The INSPIRE 8F DUAL is a modified version of the currently marketed INSPIRE 8F integrated oxygenator/hardshell venous cardiotomy reservoir system.

INDICATION FOR USE:

The intended uses for the two elements that constitute the integrated device are:

INSPIRE 8F M: Hollow Fiber Oxygenator
INSPIRE 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 8F M is intended to be used for 6 hours or less.

INSPIRE HVR DUAL: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR DUAL is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR DUAL can be used post-operatively for chest drainage.
INSPIRE HVR DUAL is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The INSPIRE 8F DUAL has the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified device.
The INSPIRE 8F DUAL integrated device will be provided with a dual chamber venous/cardiotomy reservoir (INSPIRE HVR DUAL) rather than a single chamber venous/cardiotomy reservoir (INSPIRE HVR) as for the INSPIRE 8F unmodified device.
No change to the oxygenating module has been made as a result of this modification. The INSPIRE 8F DUAL modified device is provided with oxygenating module identical with respect to the unmodified device.

No change to the intended use has been made as a result of these modifications.

The INSPIRE 8F DUAL and the INSPIRE 8F unmodified device share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. These differences do not raise any new issues of safety and effectiveness.

The INSPIRE 8F DUAL is substantially equivalent to the INSPIRE 8F on the basis of operating principles and basic function.

There are no differences in packaging type and material between unmodified and modified device.

The INSPIRE 8F DUAL is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was conducted in accordance with the relevant requirements of "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".
In vitro testing was conducted on hardshell venous/cardiotomy reservoir to demonstrate unmodified device substantial equivalency and compliance to safety and effectiveness requirements.
The modified INSPIRE 8F DUAL and unmodified INSPIRE 8F utilize identical oxygenating modules integrated with an arterial filter and a heat exchanger. This 510(k) cross references the following oxygenating module performance data previously submitted in the INSPIRE 8F (K121536): structural integrity, blood, water, gas pathway integrity, blood volume capacity, gas transfer performance/blood side pressure drop, heat exchange performance/water side pressure drop, air handling capability, filtration efficiency, hemolysis, blood compatibility, leaching of coating, flaking of coating, uniformity of coating.

The following table lists the performance and physical/mechanical integrity tests conducted to demonstrate compliance to the product's performance specifications. The INSPIRE 8F DUAL successfully met all acceptance criteria for each test.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Structural integrity
2	Physical/Mechanical	Blood pathway integrity
3	Functional/Performance	Blood rest volume
4	Functional/Performance	Air handling
5	Functional/Performance	Break-through time and volume
6	Functional/Performance	Defoaming efficiency
7	Functional/Performance	Dynamic priming volume / Hold-up
8	Functional/Performance	Filtration efficiency - venous section
9	Functional/Performance	Filtration efficiency - cardiotomy section
10	Functional/Performance	Flow rate capacity

TEST	TEST CLASSIFICATION	TEST TITLE
11	Functional/Performance	Pressure drop
12	Functional/Performance	Hemolysis
13	Functional/Performance	Blood compatibility
14	Functional/Performance	Leaching of coating
15	Functional/Performance	Flaking of coating
16	Functional/Performance	Uniformity of coating

CONCLUSIONS:

The results of in vitro studies demonstrate that the modified device performs in a manner substantially equivalent to the unmodified device with respect to the relevant functional parameters. Test results of this study demonstrate the INSPIRE 8F DUAL is equivalent to the INSPIRE 8F unmodified device with respect to device function.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2012

Sorin Group USA, Inc.
c/o Mr. Scott Light
Regulatory Affairs Manager
14401 W. 65th Way
Arvada, CO 80004

Re: K122844
Trade/Device Names: INSPIRE 8F DUAL Hollow Fiber Oxygenator with Integrated Arterial Filter and Dual Chamber Hardshell Venous/Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTN
Dated: September 14, 2012
Received: September 17, 2012

Dear Mr. Light:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K122844

Device Name: INSPIRE 8F DUAL hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir

Indication for Use:

INSPIRE 8F M: Hollow Fiber Oxygenator
INSPIRE 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 8F M is intended to be used for 6 hours or less.

INSPIRE HVR DUAL: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR DUAL is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR DUAL can be used post-operatively for chest drainage.
INSPIRE HVR DUAL is intended to be used for 6 hours or less.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122844